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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,220	05/17/2005	Juan Carlos Domingo Pedrol	OFICINA PONTI-256731	9405

21831 7590 02/25/2010

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EXAMINER	
ZAREK, PAUL E	

ART UNIT	PAPER NUMBER
1628	

NOTIFICATION DATE	DELIVERY MODE
02/25/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/535,220	DOMINGO PEDROL ET AL.	
	Examiner	Art Unit	
	Paul Zarek	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-22 and 25-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-22, 25-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application.
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claim 16 has been amended by the Applicant in correspondence filed on 11/24/2009. Claims 16-22 and 25-28 are currently pending. This is the second Office Action on the merits of the claim(s) following a request for continued examination.

RESPONSE TO ARGUMENTS

2. Claims 16-22 and 25-28 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. This rejection is moot in light of Applicants' amendment to Claim 16.

3. Claims 16-22 and 25-28 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. This rejection is moot in light of Applicants' amendment to Claim 16.

4. Amended Claims 16-22 and 25-28 are examined on their merits and the following **FINAL** rejection is made.

Claim Rejections - 35 USC § 102

5. The text of Title 35, U.S.C. § 102(e) can be found in a prior Office action.

6. Claims 16-22, and 25-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Pacioretty and Babish (US PreGrant Publication No. 2004/0106591, which claims the benefit of provisional application 60/428,246, filed on 11/22/2002, already of record).

7. Amended Claim 16 is drawn to a method of treating lipodystrophy in a patient consisting of administration of a composition comprising an effective amount of 100 mg/day or more of docosahexaenoic acid (DHA) or animal, plant, or microorganism-produced origin, wherein the patient is concomitantly receiving HAART. Claims 16 and 17 limit the daily dose of DHA to 100 mg/day or 4 g/day, respectively. Claims 18-22 limit the method to an intended result of the DHA. Claims 25 and 26 limit the route of administration to oral or parenteral, respectively. Claim 27 limits the patient to a human. Claim 28 limits the human to one infected with the HIV virus.

8. Pacioretty and Babish were described previously (see Office Action mailed 12/23/2008). Briefly, this prior art teaches a method of treating fat maldistrubtion (e.g. lipodystrophy) in an HIV-infected human patient receiving anti-retroviral therapy (ART) comprising a conjugated fatty acid, such as docosahexaenoic acid (DHA) (paragraph 0059, Claims 21 and 22). The preferred daily dose ranges from 0.05 g (e.g. 50 mg) to 20 g of conjugated fatty acids (i.e. DHA) per day (paragraph 0062). ART is defined to include all therapies used to affect HIV-1 retrovirus replication, such as reverse transcriptase and protease inhibitors. HAART utilizes both reverse transcriptase inhibitors and protease inhibitors. The route of administration of the fatty acid can be oral or parenteral (paragraph 0079, lines 5-6). Claims 18-22 limit the method to an intended result (i.e. the DHA has a hypolimemiant activity). Such "wherein" clauses are not considered to be material to patentability, as it is assumed that the ability of DHA to possess, for

example, a hypolipemiant activity is inherent in the compound. "A whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited." *Hoffer v. Microsoft Corp.*, 405 F.3d 1326, 1329, 74 USPQ2d 1481, 1483 (Fed. Cir. 2005) (MPEP § 2111.04). Therefore, Pacioretty and Babish anticipate all the limitations of the rejected claims.

9. In an after-final amendment filed on 04/02/2009, Applicants argued that Pacioretty and Babish require the presence of a thiol-containing compound or trivalent chromium, and that this prior art administers the DHA after administration of HAART. Examiner respectfully disagrees. Instant Claim 16 is drawn to a method for treating lipodystrophy consisting of administration of a composition comprising DHA. "Comprising" is open language which allows for the presence of other components, such as a thiol-containing compound or trivalent chromium. Moreover, Pacioretty and Babish explicitly state that the HAART is continued during DHA administration (para 0084). Therefore, Pacioretty and Babish anticipate all the limitations of the rejected claims.

Claim Rejections - 35 USC § 103

10. The text of Title 35, U.S.C. § 103(a) can be found in a prior Office action.

11. Claims 15-22 and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holstein, et al. (Experimental and Clinical Endocrinology and Diabetes, 2001) in view of and Connor, et al. (Annals of the New York Academy of Sciences, 1993).

12. Claims 15-22 and 25-28 are described above.

13. Holstein, et al., teach that HAART treatment causes lipodystrophy and hyperlipidemia (abstract). Lipodystrophy is defined by Stedman's Medical Dictionary as defective metabolism of fat, such that there is a dearth of subcutaneous fat. As such, hyperlipidemia can be interpreted to be a form of lipodystrophy, and treating hyperlipidemia is tantamount to treating lipodystrophy. Holdstein, et al., do not teach a method of treating lipodystrophy with DHA.

14. Connor, et al., teach that n-3 fatty acids (i.e. DHA) from fish oil has "profound hypolipidemic effects" in hypertriglyceridemic patients with hyperlipidemia (abstract). It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use a composition known to treat lipodystrophy (DHA) as a therapy for lipodystrophy, which is a known complication of HAART in HIV-infected patients. Claims 18-22 limit the method to an intended result (i.e. the DHA has a hypolipemiant activity), which is not a patentably distinguishing feature (see above 35 U.S.C. §102 rejection).

15. In an after-final amendment filed on 04/02/2009, Applicants argued that Examiner misinterpreted "lipodystrophy" and that hyperlipidemia and lipodystrophy are different clinical conditions. Examiner disagrees. Lipodystrophy is characterized by a defective metabolism of fat, a definition supported both by Stedman's Medical Dictionary and Applicants. Moreover, hyperlipidemia is almost always associated with lipodystrophy, and lipodystrophy occurs in HIV patients receiving protease inhibitors (a component of HAART) (Bernasconi, The AIDS Reader, 1999, abstract, already of record). Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to administer DHA to patients receiving HAART.

Conclusion

16. Claims 16-22 and 25-28 remain rejected.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Zarek whose telephone number is (571) 270-5754. The examiner can normally be reached on Monday-Thursday, 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PEZ

/San-ming Hui/
Primary Examiner, Art Unit 1628